41. (New) The method of claim 13, wherein when E and G^1 are independently methylene groups or do not exist and F^1 is H, G^2 is not R^N-Z^N-;

wherein R^N is any aryl or heteroaryl group and Z^N is $(CO)_{mm}$-X^N_{nn}-Y^N_{oo};

wherein mm, nn, oo are 0 or 1 and X^N,Y^N are NH, NR^{NN}, O or CH_2;

wherein R^{NN} is a short chain alkyl group (C_1 – C_{12}).

42. (New) The method of claim 41, wherein F^2 is a nitrate group; and E, F^1, G^1, G^2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions;

with the proviso that when E and G^1 are methylene groups and F^1 is H, G^2 is not a nitrate group, nor R^N-Z^N-;

wherein R^N is any aryl or heteroaryl group and Z^N is $(CO)_{mm}$-X^N_{nn}-Y^N_{oo};

wherein mm, nn, oo are 0 or 1 and X^N,Y^N are NH, NR^{NN}, O or CH_2;

wherein R^{NN} is a short chain alkyl group (C_1 – C_{12}).

REMARKS

Applicants thank the Examiner for the helpful telephone conversation which took place in June 2002. In that conversation Applicants advised the Examiner of a misalignment of the characters in substituent names in certain chemical formulae in the disclosure and in claims 33 to 40 of Applicants' previous Amendment and Response to Office Action dated 5 November 2001 (see the "In the Claims" and "Version With Markings to Show Changes Made" sections of that Response). The instant Amendment attends to correcting the alignment in those substituent names in the disclosure and claims as follows:

Page 24, formula IIIj;

Page 28, formula IIIaf;

Page 32, formula IVo;

Page 34, formula Vi;

Page 36, formula Vt;

Claim 33, formulae IIId, IIIj, and IIIaf;

Claim 34, formula IIIt;

Claim 36, formulae IVo and IVq;

Claim 38, formulae Vi, Vm, Vt, and Vu.

Applicants have also effected numerous amendments in the disclosure to to change the terms F_1, F_2, G_1, and G_2, in respect of Formulae Ia to Ic, to F^1, F^2, G^1, and G^2. Applicants have further taken the opportunity to correct typographical errors at page 4, line 8; page 9, line 7; and page 9, line 23, wherein periods (.) have been replaced with semicolons (;).

Claims

Claims 11 to 14, 16 to 20, 22, 24, 28, and 33 to 42 are in the case. Applicants acknowledge with thanks the allowance of claims 33 to 40. Claims 11, 13, and 14 have been amended as described below, and claims 33, 34, 36, and 38 have been amended as noted above. All amendments are shown on the attached sheets entitled "Version With Markings to Show Changes Made. New claims 41 and 42 have been entered. Claim 41 is derived from subject matter of claim 11 as filed, and claim 42 parallels claim 14. No new matter has been entered.

Rejections Under 35 USC § 112

Claims 11, 13, 14, 16 to 20, 22, 24, and 28 were rejected under 35 USC § 112, second paragraph. The Examiner was of the opinion that in claim 11, the limitation where substituents E, F1, F2, G1, G2 are "the same or different organic radical" is vague and indefinite. Claim 11 has been amended herein by incorporating subject matter from claim 12, and adding the additional limitation that E is a methylene group and G1 is a methylene group or does not exist. Support for this limitation can be found, for example, in claim 13, in the case where $p = 0$. Applicants submit that claim 11 as amended herein satisfies the requirements of 35 USC § 112, second paragraph.

The Examiner was also of the opinion that use in claims 11 and 13 of the terms "F_1" and "F_2" to represent substituents in the formulae renders the claims indefinite because "F" is commonly used to represent fluorine. Pursuant to Applicants' telephone discussion with the Examiner, in claims 11, 13, and 14, the terms "F_1" and "F_2" have been changed to --F^1-- and --F^2--. Further, for consistency, the additional terms "G_1" and "G_2" in respect the formulae have been changed to --G^1-- and --G^2--. Corresponding amendments have been effected throughout the disclosure as noted above. Applicants submit that claims 11 and 13, and claim 14 as amended herein are in compliance with 35 USC § 112, second paragraph. Withdrawal of the rejections and reconsideration are respectfully requested.

herein are in compliance with 35 USC § 112, second paragraph. Withdrawal of the rejections and reconsideration are respectfully requested.

Rejection Under 35 USC § 102

Claims 11, 14, 24, and 28 were rejected under 35 USC § 102(a) as anticipated by USPN 5,905,086 (Miura). The Examiner was of the opinion that the '086 patent teaches a method of treating anxiety neurosis or panic disorder, comprising administering an effective amount of a composition comprising nicorandil.

Applicants note that claim 11 as amended herein does not read on nicorandil. In view of this amendment, Applicants submit that claims 11, 14, 24, and 28 are patentable over the '086 patent and respectfuly request withdrawal of the rejection and reconsideration.

If the Examiner has any questions about the instant Amendment and Response or the application, she is asked to please telephone Stephen Scribner (Reg. No. 44,452) or Carol Miernicki Steeg (Reg. No. 39,539) at 613-533-2342.

Please charge any fees that may be required, for which no cheque is enclosed, to Deposit Account No. 17-0110.

Respectfully submitted,

Stephen J. Scribner
Reg. No. 44, 452

Date: 16 July 2002

PARTEQ Innovations
Queen's University
Kingston, Ontario K7L 3N6
CANADA
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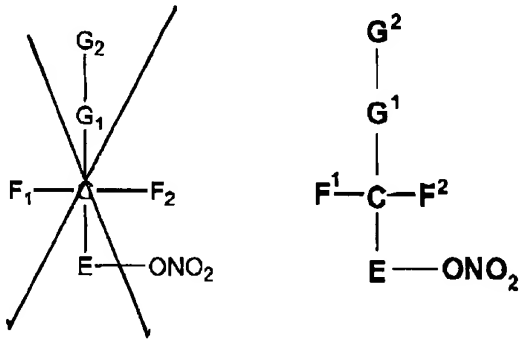
Fax. (613) 533-6853

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE DISCLOSURE:

The formula on page 3, lines 15 to 19 has been rewritten as follows:



The paragraph on page 3, lines 21 to 22 has been rewritten as follows:

in which E, ~~F_1, F_2, G_1, and G_2~~ F^1, F^2, G^1, and G^2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions;

The paragraph on page 3, lines 23 to 24 has been rewritten as follows:

with the proviso that when E and ~~G_1~~ G^1 are methylene groups and ~~F_1~~ F^1 is H, ~~G_2~~ G^2 is not a nitrate group, nor R^N-Z^N-;

The paragraph on page 4, lines 1 to 3 has been rewritten as follows:

In a preferred embodiment, ~~F_2~~ F^2 is a nitrate group and E, ~~F_1, G_1, G_2~~ F^1, G^1, G^2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions;

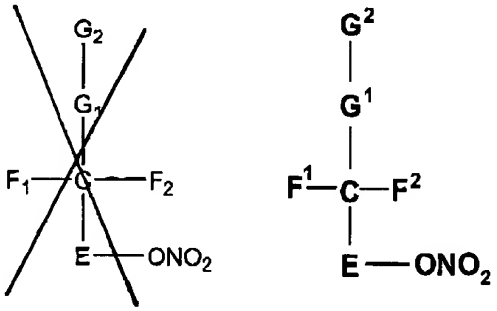
The paragraph on page 4, lines 4 to 5 has been rewritten as follows:

with the proviso that when E and ~~G_1~~ G^1 are methylene groups and ~~F_1~~ F^1 is H, ~~G_2~~ G^2 is not a nitrate group, nor R^N-Z^N-;

The paragraph on page 4, line 8 has been rewritten as follows:

wherein R^{NN} is a short chain alkyl group (C_1 – C_{12}).

The formula on page 4, lines 15 to 19 has been rewritten as follows:



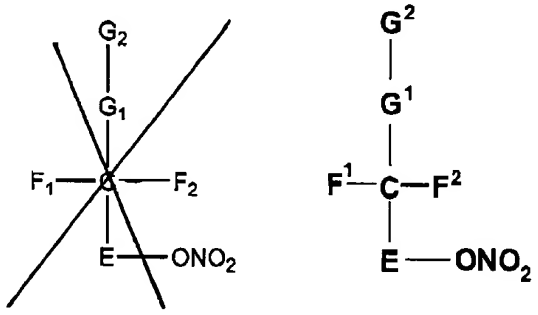
The paragraph on page 4, lines 20 to 22 has been rewritten as follows:

in which ~~F2~~ F2 is an organic radical which may be joined in a cyclic ring system with ~~G2~~ G2, and which may contain inorganic counterions; E and ~~G1~~ G1 are both methylene groups; ~~F1~~ F1 is H, and ~~G2~~ G2 is R^N-Z^N-;

The paragraph on page 4, lines 28 to 29 has been rewritten as follows:

In a preferred embodiment, ~~F2~~ F2 is a nitrate group; E and ~~G1~~ G1 are methylene groups; ~~F1~~ F1 is H, and ~~G2~~ G2 is R^N-Z^N-;

The formula on page 5, lines 12 to 16 has been rewritten as follows:



The paragraph on page 5, line 18 has been rewritten as follows:

in which E is $(R^1R^2C)_m$ and ~~G2–G1–CF1F2–~~ G2–G1–CF1F2– is R^{19}–$(R^3R^4C)_p$–$(R^{17}R^{18}C)_n$–;

The paragraph on page 8, line 19 to page 9, line 7 has been rewritten as follows:

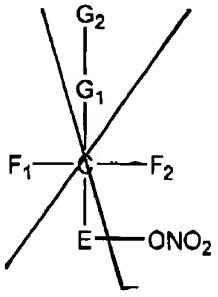
where A is selected from: a substituted or unsubstituted aliphatic group (preferably a branched, or straight-chain aliphatic moiety having from 1 to 24 carbon atoms in the chain, which optionally may contain O, S, NR^6 and unsaturations in the chain, optionally bearing from 1 to 4

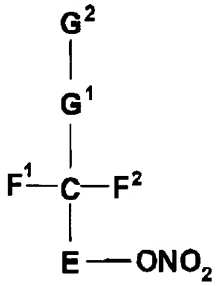
hydroxy, or nitrate, or amino or aryl, or heterocyclic groups; an unsubstituted or substituted cyclic aliphatic moiety having from 3 to 7 carbon atoms in the aliphatic ring, which optionally may contain O, S, NR^6 and unsaturations in the ring, optionally bearing from 1 to 4 hydroxy, or nitrate, or amino or aryl, or heterocyclic groups; an unsubstituted or substituted aliphatic moiety constituting a linkage of from 0 to 5 carbons, between R^1 and R^3 and/or between R^{17} and R^4, which optionally may contain O, S, NR^6 and unsaturations in the linkage, and optionally bearing from 1 to 4 hydroxy, or nitrate, or amino or aryl, or heterocyclic groups); a substituted or unsubstituted aliphatic group (preferably a branched, cyclic or straight-chain aliphatic moiety having from 1 to 24 carbon atoms in the chain), containing carbonyl linkages (e.g., C=O, C=S, C=NOH), which optionally may contain O, S, NR^6 and unsaturations in the chain, optionally bearing from 1 to 4 hydroxy, or nitrate, or amino or aryl, or heterocyclic groups; a substituted or unsubstituted aryl group; a heterocyclic group; amino (including alkylamino, dialkylamino (including cyclic amino, diamino and triamino moieties), arylamino, diarylamino, and alkylarylamino); hydroxy; alkoxy; a substituted or unsubstituted aryloxy;

The paragraph on page 9, lines 20 to 23 has been rewritten as follows:

R^6, R^7, R^8, R^9, R^{10}, R^{11}, R^{12}, R^{13}, R^{14}, R^{15}, R^{16} are the same or different alkyl or acyl groups containing 1 - 24 carbon atoms which may contain 1 - 4 ONO_2 substituents; or C_1 - C_6 connections to R^1 – R^4 in cyclic derivatives; or are each independently hydrogen; a nitrate group; or W;

The formula on page 19, lines 15 to 19 has been rewritten as follows:

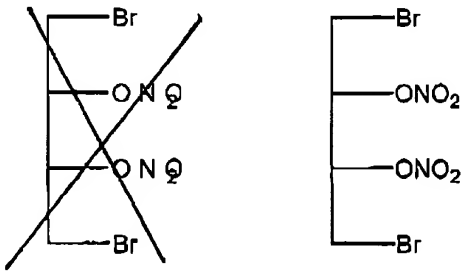




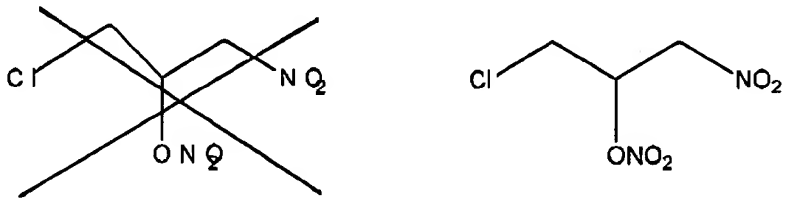
The paragraph on page 19, lines 20 to 21 has been rewritten as follows:

wherein: E, ~~F_1, F_2, G_1, G_2~~ F^1, F^2, G^1, G^2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions.

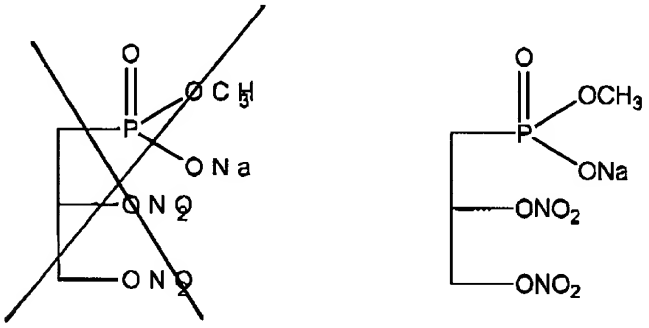
Formula IIIj on page 24 has been rewritten as follows:



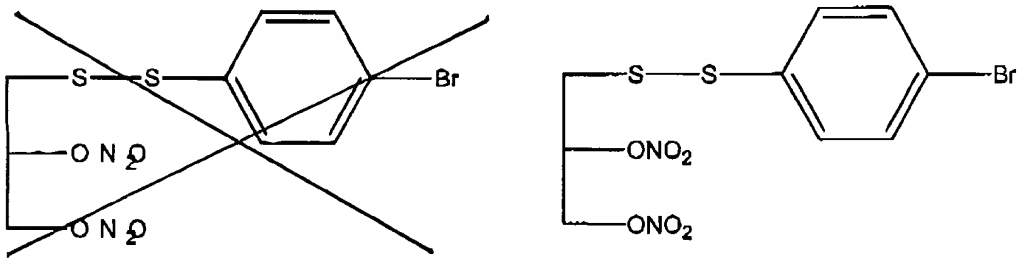
Formula IIIaf on page 28 has been rewritten as follows:



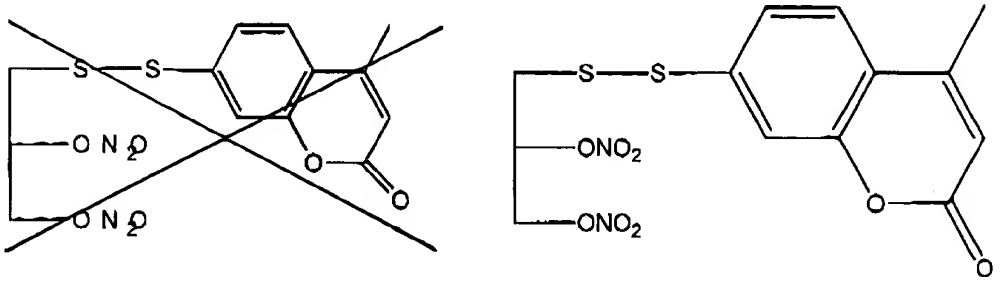
Formula IVo on page 32 has been rewritten as follows:



Formula Vi on page 34 has been rewritten as follows:



Formula Vt on page 36 has been rewritten as follows:

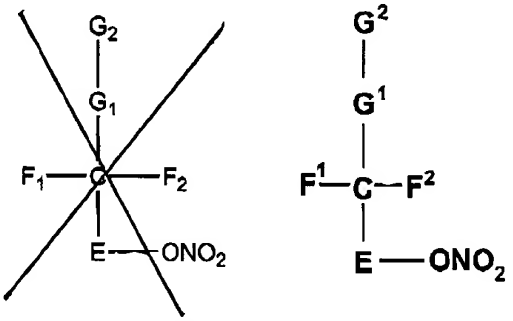


IN THE CLAIMS:

Claims 11, 13, 14, 33, 34, 36, and 38 have been amended as follows:

11. A method for providing sedation, mitigating anxiety or providing anaesthesia in a subject in need thereof, comprising administering to a subject an effective amount of a therapeutic compound, wherein the therapeutic compound is of the formula (Ia):

(Ia)



~~in which E, F_1, F_2, G_1, G_2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions, but which do not contain an organic nitrate group;~~

~~with the proviso that when E and G_1 are methylene groups and F_1 is H, G_2 is not a nitrate group, nor R^N-Z^N;~~

~~wherein R^N is any aryl or heteroaryl group and Z^N is $(CO)_{mm}$-X^N_{nn}-Y^N_{oo};~~

~~wherein mm, nn, oo are 0 or 1 and X^N,Y^N are NH, NR^{NN}, O or CH_2;~~

in which F^2 is an organic radical which may be joined in a cyclic ring system with G^2, and which may contain inorganic counterions, but is not a nitrate group; E is a methylene group and G^1 is a methylene group or does not exist; F^1 is H; and G^2 is R^N-Z^N;

wherein R^N is an organic radical possessing a heteroaryl group containing P or S atoms

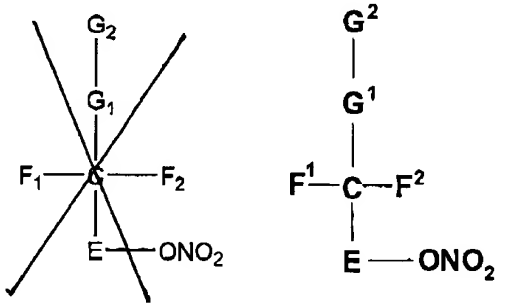
where said P or S are positioned β, γ, or δ to a nitrate group as identified in formula I; and Z^N is W^N_{mm}-X^N_{nn}-Y^N_{oo};

wherein mm, nn, oo are 0 or 1 and W^N, X^N, Y^N are NH, NR^{NN}, CO, O or CH_2;

wherein R^{NN} is a short chain alkyl group (C_1 - C_{12}).

13. A method for providing sedation, mitigating anxiety or providing anaesthesia in a subject in need thereof, comprising administering to a subject an effective amount of a therapeutic compound, wherein the therapeutic compound is of the formula (Ic):

(Ic)



in which E is $(R^1R^2C)_m$ and ~~G_2-G_1-CF_1F_2-~~ G^2-G^1-CF^1F^2- is R^{19}-$(R^3R^4C)_p$-$(R^{17}R^{18}C)_n$-;

wherein: m, n, p are integers from 0 to 10;

$R^{3,17}$ are each independently hydrogen, a nitrate group, or A; and

$R^{1,4}$ are each independently hydrogen, or A;

where A is selected from a substituted or unsubstituted aliphatic group (comprising a branched or straight-chain aliphatic moiety having from 1 to 24 carbon atoms in the chain, which optionally may contain O, S, NR^6 and unsaturations in the chain, optionally bearing from 1 to 4 hydroxy, nitrate, amino, aryl, or heterocyclic groups; an unsubstituted or substituted cyclic aliphatic moiety having from 3 to 7 carbon atoms in the aliphatic ring, which optionally may contain O, S, NR^6 and unsaturations in the ring, optionally bearing from 1 to 4 hydroxy, nitrate, amino, aryl, or heterocyclic groups; an unsubstituted or substituted aliphatic moiety constituting a linkage of from 0 to 5 carbons, between R^1 and R^3 and/or between R^{17} and R^4, which optionally may contain O, S, NR^6 and unsaturations in the linkage, and optionally bearing from 1 to 4 hydroxy, nitrate, amino, aryl, or heterocyclic groups); a substituted or unsubstituted aliphatic group (comprising a branched, cyclic or straight-chain aliphatic moiety having from 1 to 24 carbon atoms in the chain) containing carbonyl linkages (C=O, C=S, C=NOH), which optionally may contain O, S, NR^6 and unsaturations in the chain, optionally bearing from 1 to 4 hydroxy, nitrate, amino, aryl, or

heterocyclic groups; a substituted or unsubstituted aryl group; a heterocyclic group; an amino group selected from alkylamino, dialkylamino, cyclic amino, diamino and triamino moieties, arylamino, diarylamino, and alkylarylamino; hydroxy; alkoxy; a substituted or unsubstituted aryloxy;

wherein X is F, Br, Cl, NO_2, CH_2, CF_2, O, NH, NMe, CN, NHOH, N_2H_3, $N_2H_2R^{13}$, $N_2HR^{13}R^{14}$, N_3, S, SCN, $SCN_2H_2(R^{15})_2$, $SCN_2H_3(R^{15})$, $SC(O)N(R^{15})_2$, $SC(O)NHR^{15}$, SO_3M, SH, SR^7, SO_2M, $S(O)R^8$, $S(O)_2R^9$, $S(O)OR^8$, $S(O)_2OR^9$, PO_2HM, PO_3HM, PO_3M_2, $P(O)(OR^{15})(OR^{16})$, $P(O)(OR^{16})(OM)$, $P(O)(R^{15})(OR^8)$, $P(O)(OM)R^{15}$, CO_2M, CO_2H, CO_2R^{11}, C(O), $C(O)R^{12}$, $C(O)(OR^{13})$, PO_2H, PO_2M, $P(O)(OR^{14})$, $P(O)(R^{13})$, SO, SO_2, $C(O)(SR^{13})$, SR^5, SSR^7 or SSR^5;

Y is F, Br, Cl, CH_3, CF_2H, CF_3, OH, NH_2, NHR^6, NR^6R^7, CN, NHOH, N_2H_3, $N_2H_2R^{13}$, $N_2HR^{13}R^{14}$, N_3, S, SCN, $SCN_2H_2(R^{15})_2$, $SCN_2H_3(R^{15})$, $SC(O)N(R^{15})_2$, $SC(O)NHR^{15}$, SO_3M, SH, SR^7, SO_2M, $S(O)R^8$, $S(O)_2R^9$, $S(O)OR^8$, $S(O)_2OR^9$, PO_2HM, PO_3M_2, $P(O)(OR^{15})(OR^{16})$, $P(O)(OR^{16})(OM)$, $P(O)(R^{15})(OR^8)$, $P(O)(OM)R^{15}$, CO_2M, CO_2H, CO_2R^{11}, $C(O)R^{12}$, $C(O)(OR^{13})$, $C(O)(SR^{13})$, SR^5, SSR^7 or SSR^5, or does not exist;

R^2, R^5, R^{18}, R^{19} are optionally hydrogen, A or X-Y;

R^6, R^7, R^8, R^9, R^{11}, R^{12}, R^{13}, R^{14}, R^{15}, R^{16} are the same or different alkyl or acyl groups containing 1-24 carbon atoms which may contain 1-4 ONO_2 substituents; or C_1 - C_6 connections to R^1 – R^4 in cyclic derivatives which may contain 1-4 ONO_2 substituents; or are each independently hydrogen, a nitrate group or A;

M is H, Na^+, K^+, NH_4^+, $N^+H_kR^{11}{}_{(4-k)}$ where k is 0-3; or other pharmaceutically acceptable counterion;

and with the proviso that when m = n = p = 1 and R^{19}, R^2, R^{18}, R^1 = H and R^{17}, R^3 are nitrate groups, R^4 is not H.

14. The method of claim 11, wherein ~~F_2~~ F^2 is a nitrate group; and E, ~~F_1, G_1, G_2~~ F^1, G^1, G^2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions;

with the proviso that when E and ~~G_1~~ G^1 are methylene groups and ~~F_1~~ F^1 is H, ~~G_2~~ G^2 is not a nitrate group, nor R^N-Z^N-;

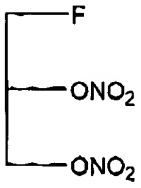
wherein R^N is any aryl or heteroaryl group and Z^N is $(CO)_{mm}$-$X^N{}_{nn}$-$Y^N{}_{oo}$;

wherein mm, nn, oo are 0 or 1 and X^N,Y^N are NH, NR^{NN}, O or CH_2;

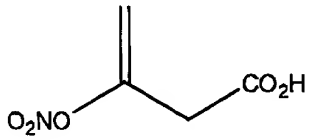
wherein R^{NN} is a short chain alkyl group (C_1 – C_{12}).

33. A method of providing sedation or mitigating anxiety in a subject in need thereof, comprising administering to a subject an effective amount of a therapeutic compound selected from the group consisting of:

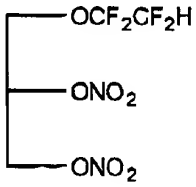
IIIa



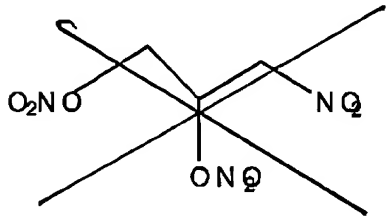
IIIb

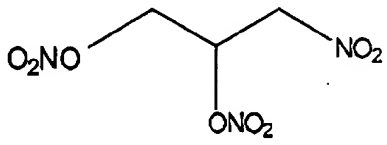


IIIc

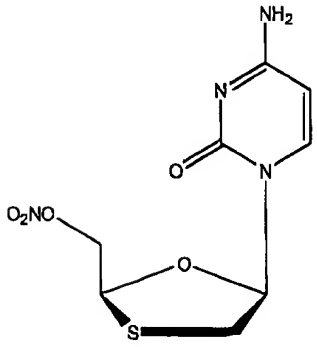


IIId

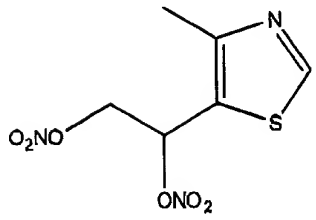




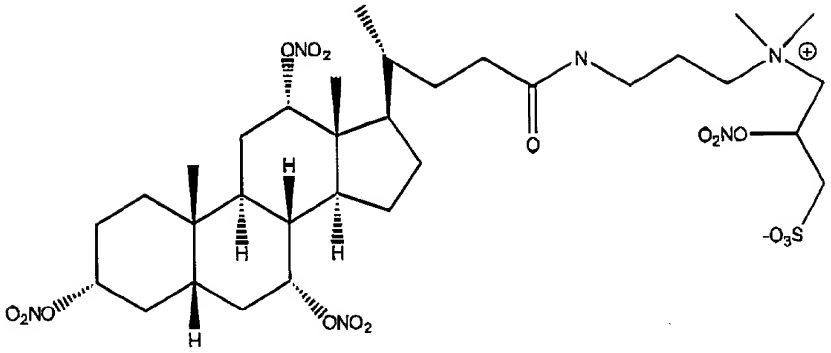
IIIe



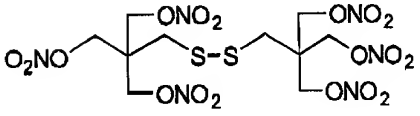
IIIf



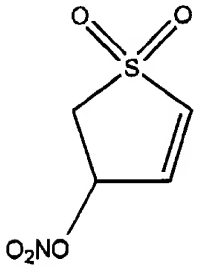
IIIg



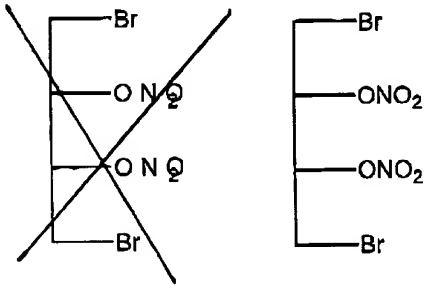
IIIh



IIIi



IIIj



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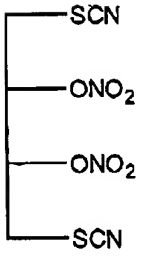

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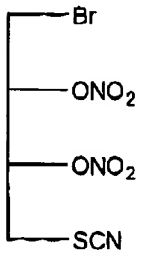

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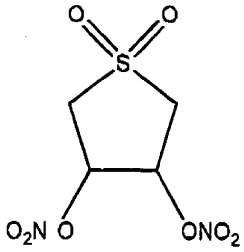

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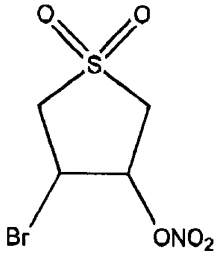

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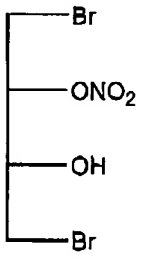

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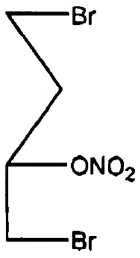

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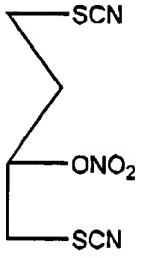

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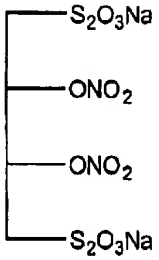

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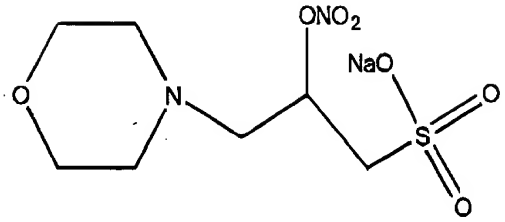

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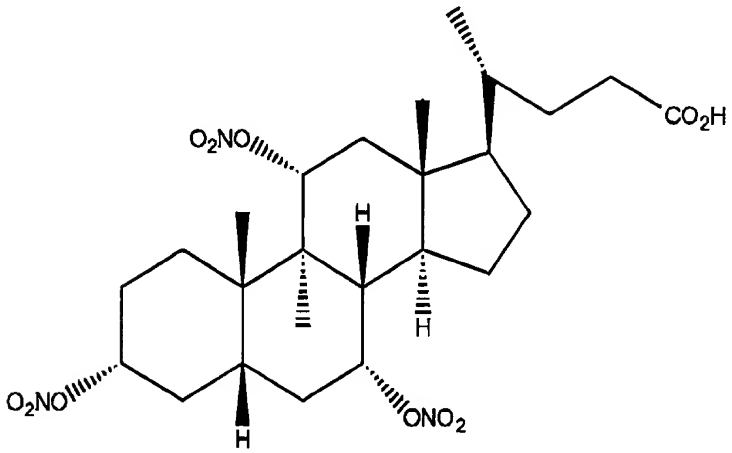

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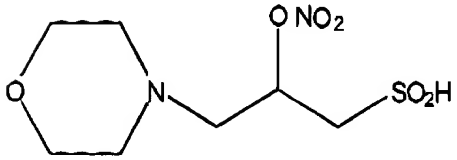

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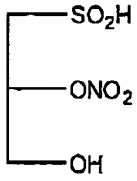

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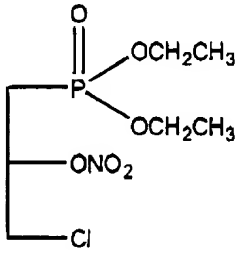

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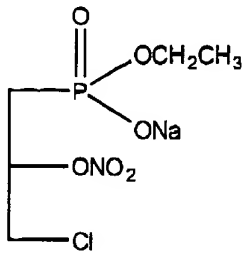
IIIx 

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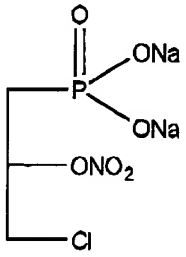
IIIy 

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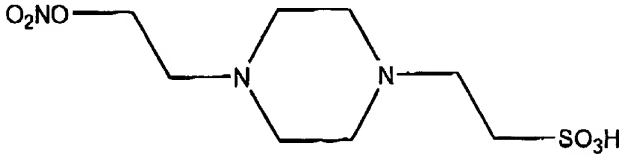
IIIz 

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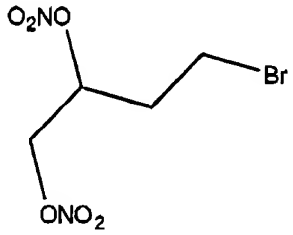
IIIaa 

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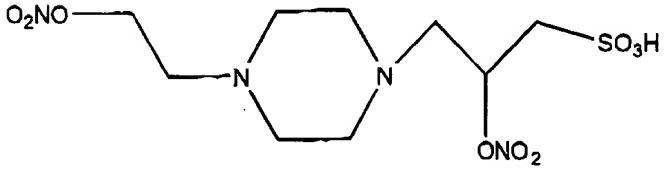
IIIab 

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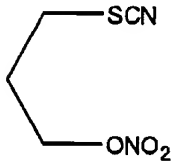
IIIac 

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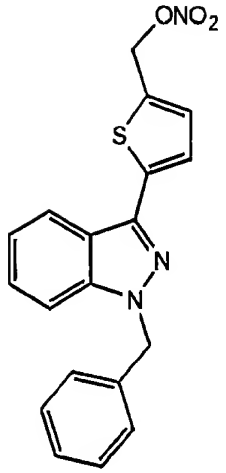
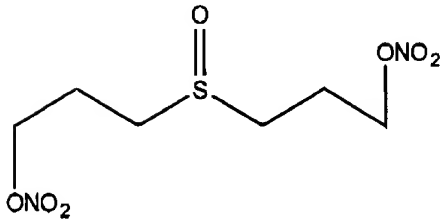
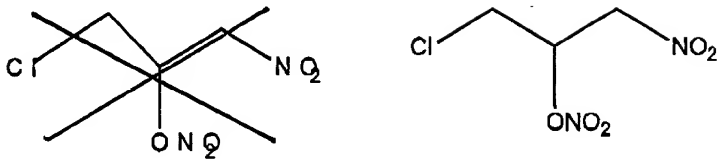
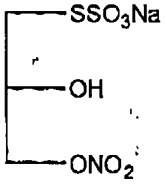
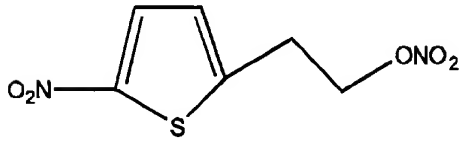
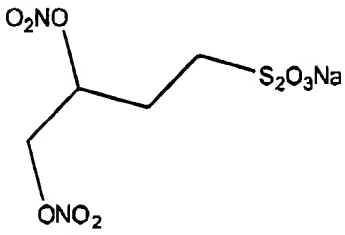
IIIad 

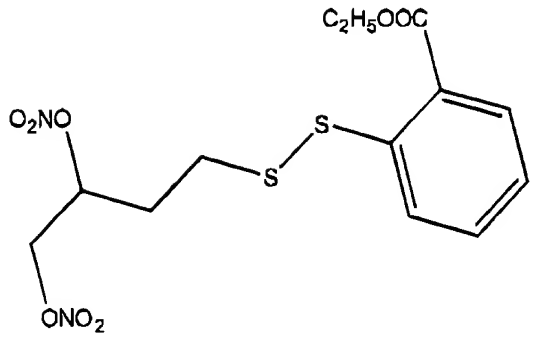
IIIae 

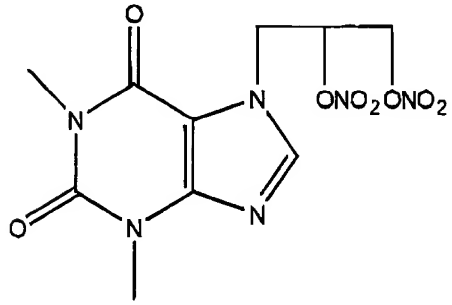
IIIaf 

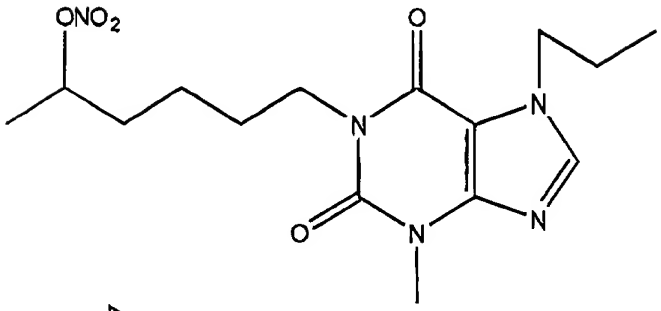
IIIag 

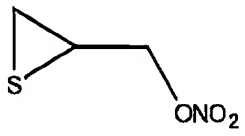
IIIah 

IIIai 

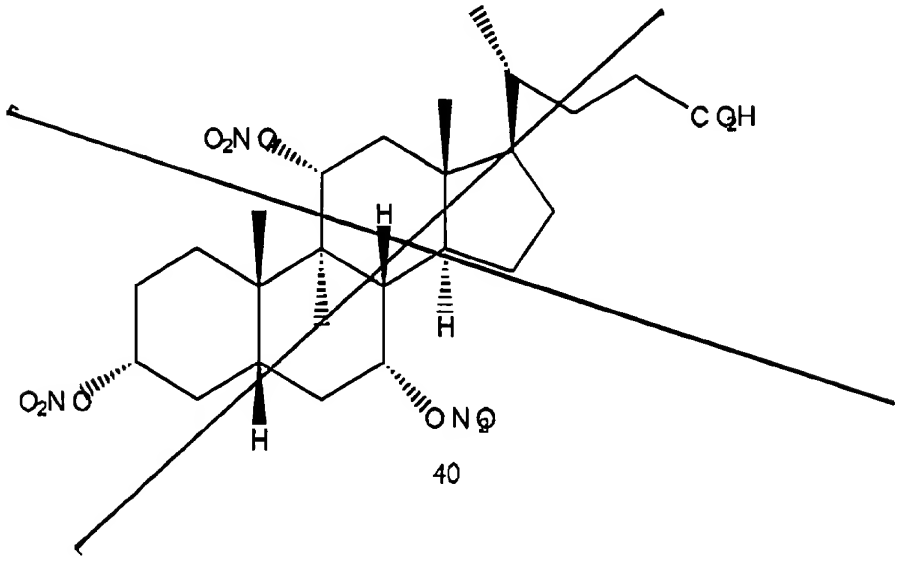
IIIaj 

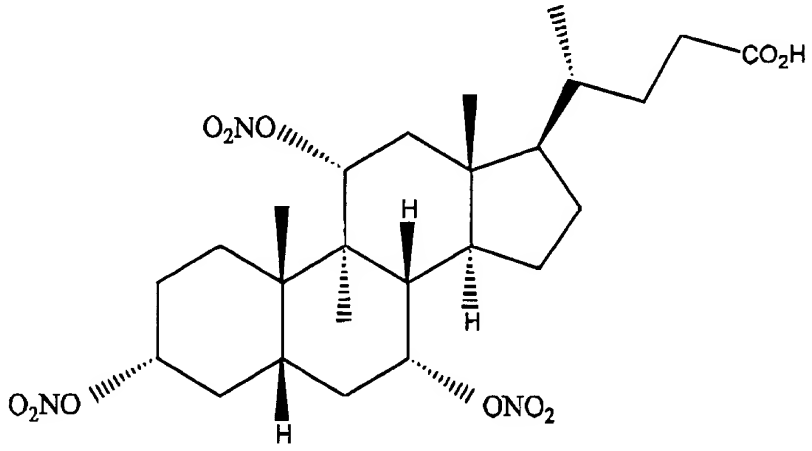
IIIak 

IIIal  , and

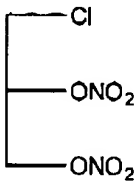
IIIam 

34. The method of claim 33, wherein the compound has the formula IIIt:





36. A method of providing sedation or mitigating anxiety in a subject in need thereof, comprising administering to a subject an effective amount of a therapeutic compound selected from the group consisting of:

IVa 

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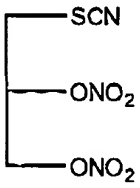
IVb 

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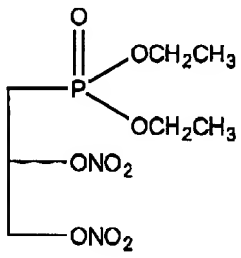
IVc 

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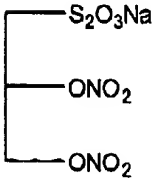
IVd 

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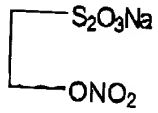
IVe 

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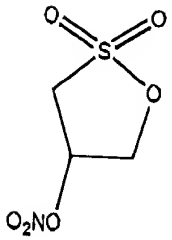
IVf 

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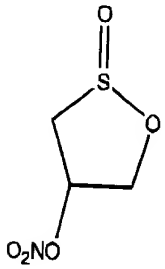
IVg 

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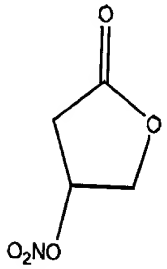
IVh 

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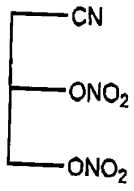
IVi 

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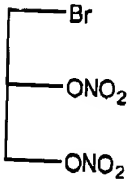
IVj 

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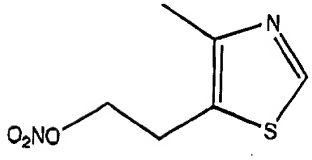
IVk 

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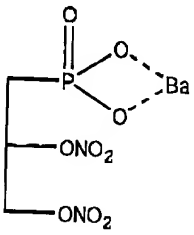
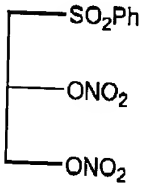
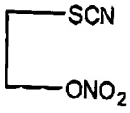
IVl



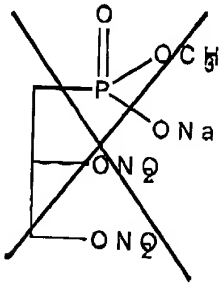
IVm

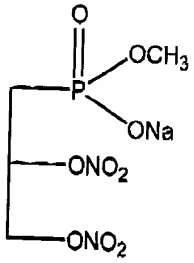


IVn



IVo





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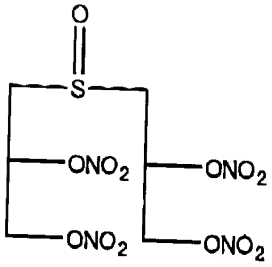
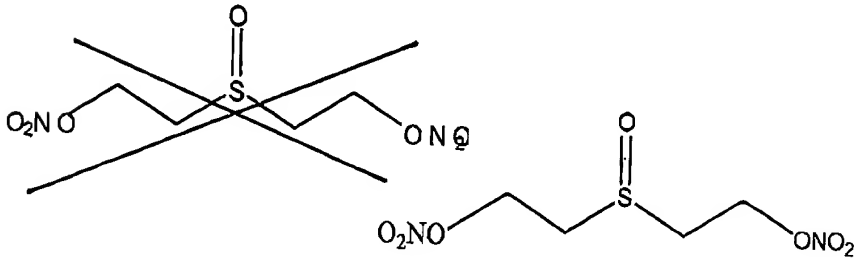
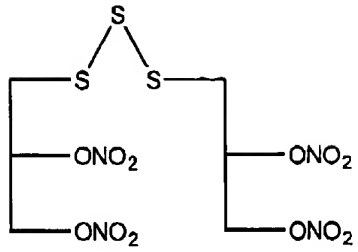
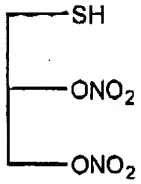
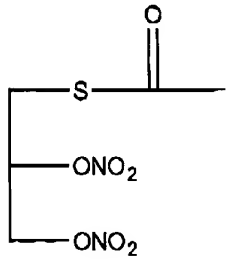


IVq

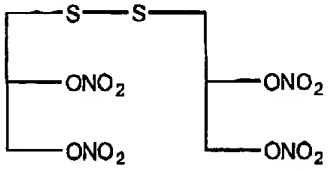


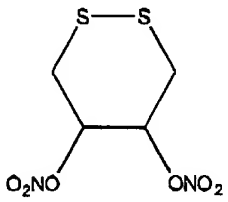
IVr  ,

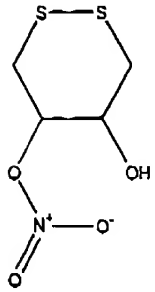
IVs  , and

IVt  .

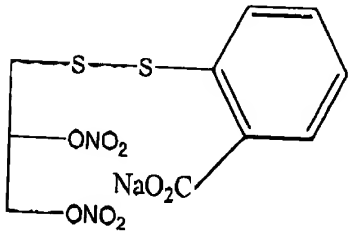
38. A method of mitigating anxiety in a subject in need thereof, comprising administering to a subject an effective amount of a therapeutic compound selected from the group consisting of:

Va  ,

Vb  ,

Vc  ,

Vd



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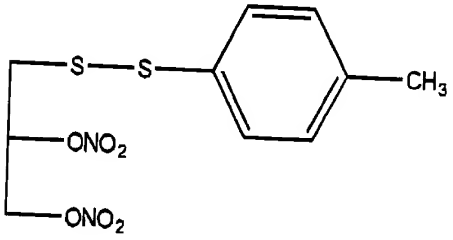

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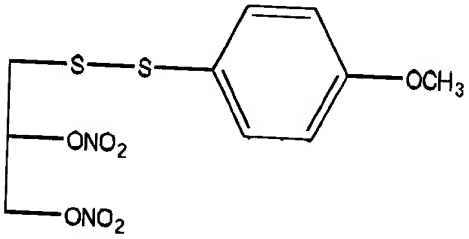

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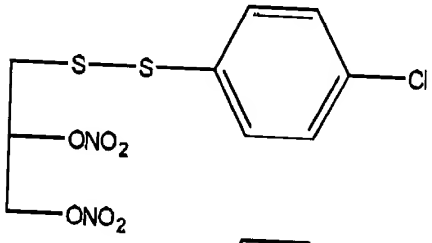

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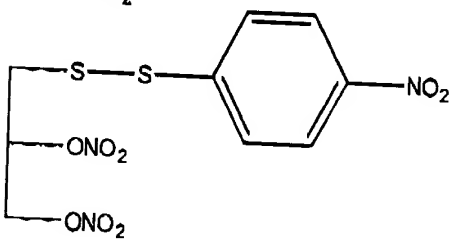

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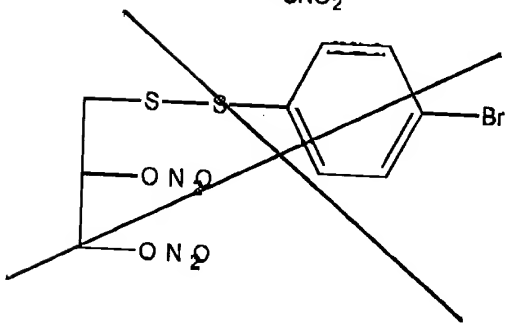

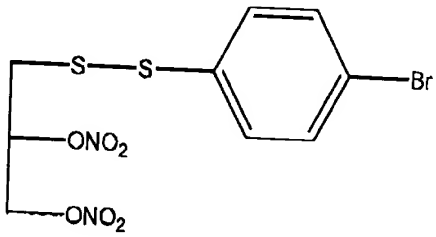

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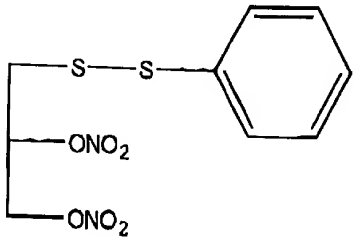

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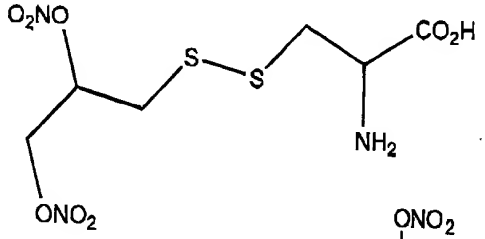

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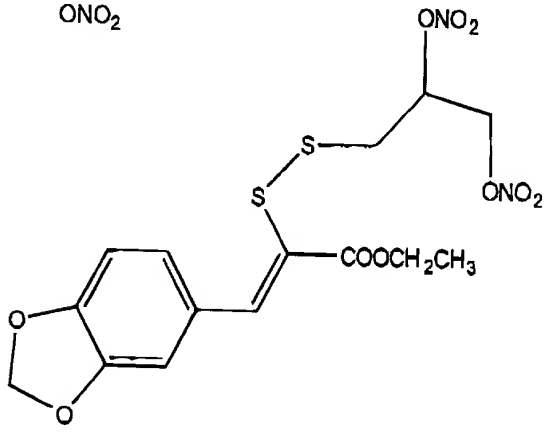

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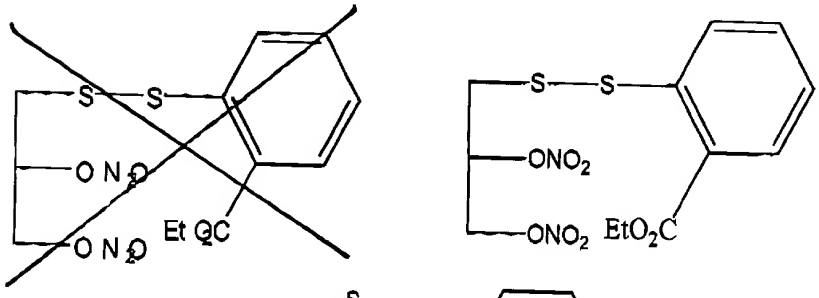

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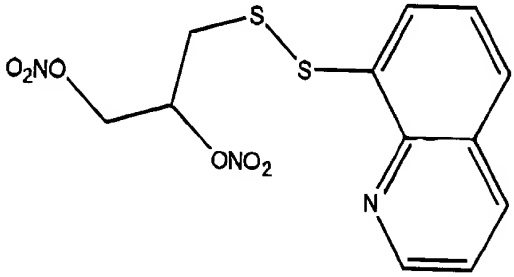

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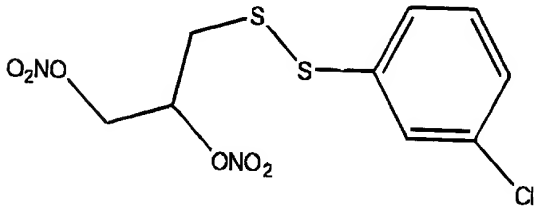
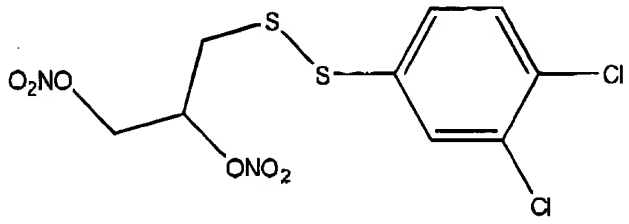


Vp 

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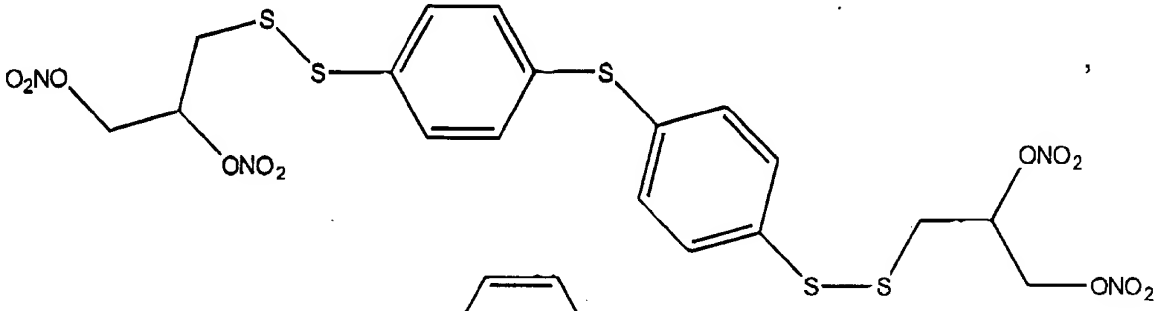
Vq 

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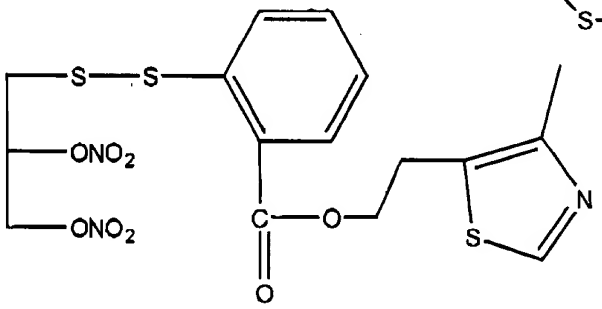
Vr 

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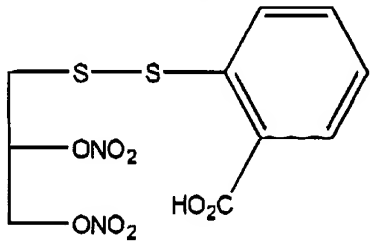
Vs 

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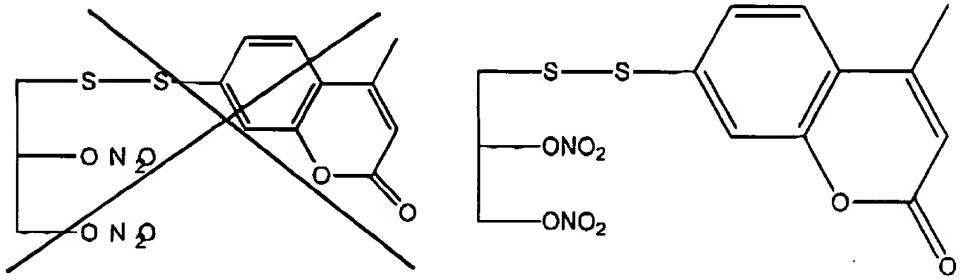
Vt 

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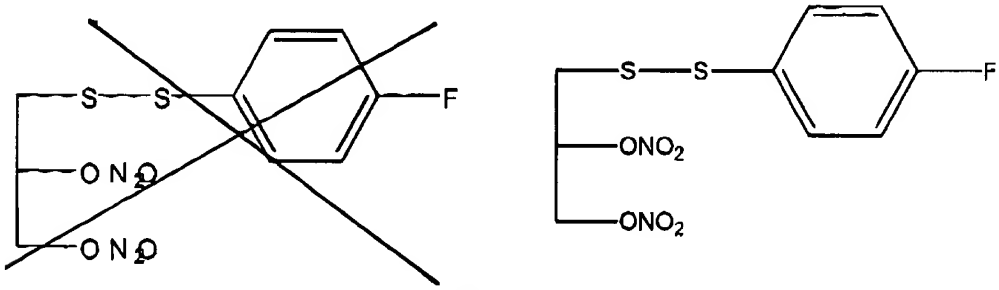
Vu 

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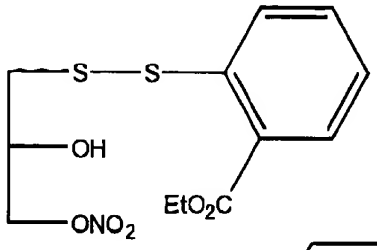
Vv 

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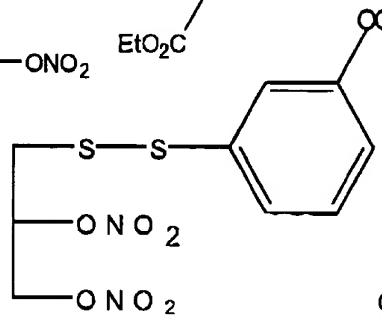
Vw 

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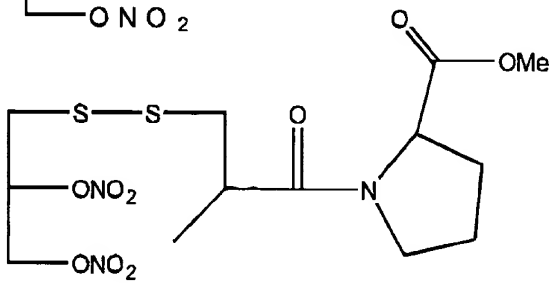
Vx 

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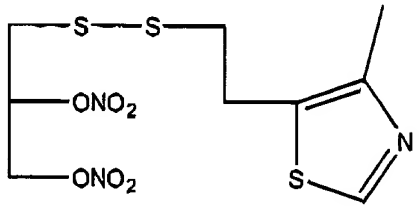
Vy 

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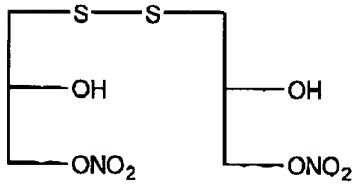
Vz 

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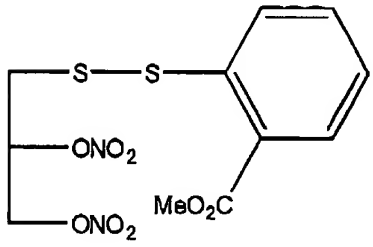
Vaa 

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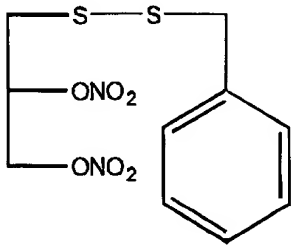

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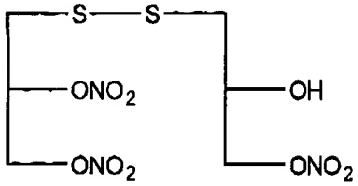

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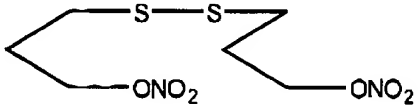

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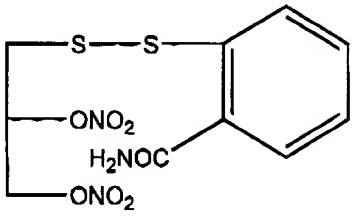

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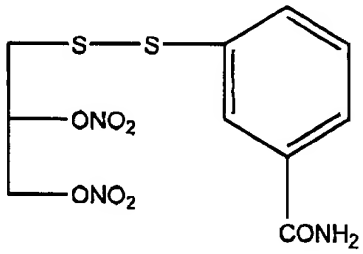

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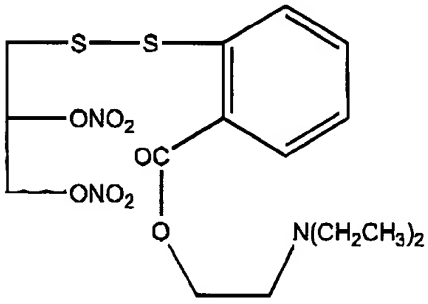

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Claims 41 and 42 have been entered as follows:

41. The method of claim 13, wherein when E and G^1 are independently methylene groups or do not exist and F^1 is H, G^2 is not R^N-Z^N-;

wherein R^N is any aryl or heteroaryl group and Z^N is $(CO)_{mm}$-X^N_{nn}-Y^N_{oo};

wherein mm, nn, oo are 0 or 1 and X^N,Y^N are NH, NR^{NN}, O or CH_2;

wherein R^{NN} is a short chain alkyl group (C_1 - C_{12}).

42. The method of claim 41, wherein F^2 is a nitrate group; and E, F^1, G^1, G^2 are the same or different organic radicals which may be joined in cyclic ring systems, and which may contain inorganic counterions;

with the proviso that when E and G^1 are methylene groups and F^1 is H, G^2 is not a nitrate group, nor R^N-Z^N-;

wherein R^N is any aryl or heteroaryl group and Z^N is $(CO)_{mm}$-X^N_{nn}-Y^N_{oo};

wherein mm, nn, oo are 0 or 1 and X^N,Y^N are NH, NR^{NN}, O or CH_2;

wherein R^{NN} is a short chain alkyl group (C_1 - C_{12}).